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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/001,367	10/30/2001	Barbara A. Brewitt	20371.0004c4	3277

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Ann W. Speckman
SPECKMAN LAW GROUP
Suite 100
1501 Western Avenue
Seattle, WA 98101

EXAMINER

SEHARASEYON, JEGATHEESAN

ART UNIT PAPER NUMBER

1647

DATE MAILED: 06/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/001,367	BREWITT, BARBARA A.	
	Examiner	Art Unit	
	Jegatheesan Seharaseyon, Ph.D	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 February 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,9-11 and 13-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-3, 9-11, 13-23, 26 and 29-30 is/are rejected.
- 7) ☒ Claim(s) 24,25,27 and 28 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. This office action is in response to the amendment and response filed on 2/28/2005.

Claims 4-8 and 12 have been cancelled. Claims 1-3, 9-11 and 13-20 have been amended. Thus, claims 1-3, 9-11 and 13-30 are pending.

2. The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office action.

3. The Office acknowledges the change in title.

Claim Rejections - 35 USC § 112

4. The rejection of claims 13-18 under 35 U.S.C. §112, second paragraph, as being indefinite, for failing to particularly point out and distinctly claim the subject matter is withdrawn due to Applicants' persuasive arguments.

5. The rejection of claim 5 under 35 U.S.C. §112, first paragraph, as lacking in enabling disclosure is withdrawn due to Applicants' cancellation of the claims.

Double patenting

6. Applicants have provided a terminal disclaimer under 37 CFR 1.321(c) to overcome the pending rejections of claims 1-20 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent NO. 5, 629, 286. Therefore the pending rejections are withdrawn.

7. The pending rejections of claims 1-20 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-19 of U.S. Patent NO. 6, 239, 105 is withdrawn because of Applicants' persuasive arguments.

Claim Rejections - 35 USC § 102

8. The rejection of claims 1, 9, 10, 14 and 30 (new) under 35 USC § 102(b) as being anticipated by Antoniades et al. (U.S. Patent NO. 5,035,887) are maintained for reasons indicated in the previous Office Action dated 8/24/2004, page 6. Applicant's arguments filed on 2/28/05 pages 13-14 have been fully considered but are not deemed to be persuasive. Applicant argues that the claim 1 amendment that the preparation is for oral administration makes it free of the prior art. However, "for oral administration" is encompassed by the prior art. The pharmaceutically acceptable carriers referred in the prior art such as liquids and gels can also be used for oral administration (column 2, lines 26-29). In addition, the prior art also encompasses homeopathic potency by using 500ng-1µg of the IGF-1 (see response page 13, 3rd paragraph). In addition, Antoniades et al. also teach the inclusion of IGF-1 in a gel (column 5, lines 5-15) meeting the limitation of claim 9. In addition, an inert gel could also be a tablet for oral administration, meeting the limitation of claim 30. The reference also teaches purified IGF-1 that is 90% or greater meeting the limitation of claim 10. Finally, as Applicant has indicated in the response the prior art also teaches a preparation which along with IGF-1 also contains IL-1 or PDGF. Therefore, the rejection of claims 1, 9, 10, 14 and 30 (new) under 35 USC § 102(b) as being anticipated by Antoniades et al. (U.S. Patent NO. 5,035,887) are maintained.

Claim Rejections - 35 USC § 103

9. The rejection of claims 13, 15-18 and 21-23 (new) under 35 U.S.C. 103(a) as being unpatentable over Antoniades et al. (U. S. Patent No. 5, 035, 887) in view of Vithoulkas

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et al. (1981) is maintained. Applicant's arguments filed on 2/28/05 page 14 have been fully considered but are not deemed to be persuasive. Applicant asserts that the combination of references do not render obvious the instant invention of preparation containing a homeopathic potency of purified IGF-1 suitable for oral administration.

However, as indicated above in paragraph 8 and the previous Office Action dated 8/24/2004 pages 6-7, oral administration is encompassed by the prior art and thus the rejection of record is maintained. Furthermore, Vithoulkas et al. (1981) reference was used teach the various potencies used in homeopathy for therapeutic purposes.

Therefore the rejection of claims 13,15-18 and 21-23 (new) under 35 U.S.C. 103(a) as being unpatentable over Antoniades et al. (U. S. Patent No. 5, 035, 887) in view of Vithoulkas et al. (1981) is maintained.

10.The rejection of claims 2, 3, 11, 20 and 29 (new) under 35 U.S.C. 103(a) as being unpatentable over Antoniades et al. (U. S. Patent No. 5, 035, 887) in view of Clark et al. (U. S. Patent No. 5, 597, 797) is maintained. Applicant's arguments filed on 2/28/05 page 14 have been fully considered but are not deemed to be persuasive. Applicant asserts that the combination of references do not render obvious the instant invention of preparation containing a homeopathic potency of purified IGF-1 suitable for oral administration. However, as indicated above in paragraph 8 and the previous Office Action dated 8/24/2004 pages 6-7, oral administration is encompassed by the prior art and thus the rejection of record is maintained. In addition, Clark et al. also describe preparations, which contain various combinations including GH and amino acids. In

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addition, it also teaches that these are recombinant human proteins that are purified (column 8, lines 11-65 and example III). Clark et al. also describe that the composition is in liquid form including an aqueous solution (column 15, lines 15-30). Therefore the rejection of claims 2, 3, 11, 20 and 29 (new) under 35 U.S.C. 103(a) as being unpatentable over Antoniades et al. (U. S. Patent No. 5, 035, 887) in view of Clark et al. (U. S. Patent No. 5, 597, 797) is maintained.

11. The rejection of claim 19 under 35 U.S.C. 103(a) as being unpatentable over Antoniades et al. (U. S. Patent No. 5, 035, 887) in view of Whitson-Fischman et al. (U. S. Patent No. 5, 162, 037) is maintained. Applicant's arguments filed on 2/28/05 page 15 have been fully considered but are not deemed to be persuasive. Applicant asserts that the combination of references do not render obvious the instant invention of preparation containing a homeopathic potency of purified IGF-1 suitable for oral administration. The Whitson-Fischman et al. reference was included to describe a homeopathic medicament for the treatment of broad-spectrum viral infection containing herb hypericum (column 17, lines 35-40). Therefore the rejection of claim 19 under 35 U.S.C. 103(a) as being unpatentable over Antoniades et al. (U. S. Patent No. 5, 035, 887) in view of Clark et al. (U. S. Patent No. 5, 597, 797) is maintained.

12. New claim rejection necessitated by Applicants addition of claims.

Claim Rejections - 35 USC § 112

13. Claim 26 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant

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regards as the invention. Specifically it not clear what a "30C+1M" potency would be. It also suggested that Applicant keep the potency in a single unit like "C". Thus 1M would be 1000C.

Claim Objections

14. Claims 24, 25, 27 and 28 are objected because they depend on rejected claim 1. However, if these claims are written as independent claims, it could be allowable over prior art.

15. **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


Contact information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon whose telephone number is 571-272-0892. The examiner can normally be reached on M-F: 8:30-4:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JS 06/05


JANET ANDRES
PRIMARY EXAMINER